IN THE DRAWINGS

Fig. 3 has been amended to delete label 6-6 on the dotted line labeled 5-5.

Fig. 4 has been amended to include the worm 132 and its interaction with the teeth 144.

Attachment: Replacement Sheets

REMARKS

As an initial matter, the Examiner objected to the drawings on the grounds that the worm 132 and teeth 144 features of the invention were unclear in the specification and drawings. Applicants submit that the worm 132 and its interaction with the teeth 144 are clearly defined in the specification and Figs. 1 and 4, and that this interaction and placement would be understood by one skilled in this art. "The teeth 144 are dimensioned so as to mesh with the worm. . . The bracket 136 is assembled into the housing 114 by inserting the bottom wall 140 through opening 124 until the teeth 144 mesh with worm 132." (Specification p. 9). That said, Fig. 4 has been amended for further clarification to show the worm 132 and its interaction with the teeth 144, support for which is found in claims 7, 19, 31, 46 and paragraphs 0030 and 0035 of the specification. In addition, the Examiner made an objection to Fig. 3 as having one line with two labels. Fig. 3 has been amended to delete label 6-6.

Paragraph 0017 has been amended to clarify that Fig. 4 is a top plan view of one component of an assembly for varus-valgus alignment of the resection guide, and shows the worm 132 interaction with the teeth 144. Paragraph 0019 of the specification has been amended to clarify that Fig. 6 is a cross-sectional view of Fig. 5 taken along line 5-5. Paragraph 0030 has been amended to clarify the function of the worm 132 and its meshed relationship with teeth 144. Claims 14, 26, and 42 have been amended to clarify that the third assembly is attached to the instrument guide. Claim 42 has also been amended to include the limitations of claim 44 (now cancelled). Claims 45, 46 and 48 have been amended to recite proper dependencies. No new matter has been added. Entry of these amendments is respectfully requested.

35 U.S.C. § 102(b)

The Examiner has rejected claims 1-6, 11-18, 23-30, 35-45 and 48-51 as anticipated under 35 U.S.C. § 102(b), over *Pohl* (U.S. Patent No. 4,703,751). Of the pending claims, claims 1, 14, 26, 37, 42 and 50 have been presented in independent form. The Examiner contends that *Pohl* discloses each and every limitation of the rejected claims. For example, the Examiner believes that *Pohl* discloses an apparatus (10) comprising a guide plate (18) and alignment means along a translational path and two rotational paths, boss (44) and rod (14), wherein rod (14) allows rotation about a first rotational path in controlled increments by turning knob (32). Applicants respectfully traverse the rejection.

Pohl is directed to a method and apparatus for resecting a distal femoral surface. In *Pohl*, the cutting plate (18), when coupled to the support plate (36) can be "pivoted slightly" about rod (14). (*Pohl* col. 6, lns. 58-64). In contrast to the Examiner's contention, *Pohl* does not disclose any assembly that would allow for "controlled increments", as defined in the specification, for rotating the cutting plate and/or support plate about rod (30). Simply put, the Examiner's reference to knob (32) as a controlled increment assembly is inaccurate. (Office Action p. 4). The knob (32) is merely affixed to the end of the rod (14) after the cutting plate (18) and support plate (36) are mounted thereon. (*Pohl* col. 5, lns. 45-48; col. 6, lns. 54-57). While the cutting plate (18) is rotatable relative to the support plate (36), any rotation of the rod (14) or knob (32) would not result in rotation of the cutting plate (18) or support plate (36). In fact, the rod would not be rotatable at all as it is inserted through the intercondylar canal of the bone. Thus, the cutting plate (18) and support plate (36) can only be translated along the rod via the reference bar (20) by rotation of bolts (104) and (106).

Claim 1 of the present application recites an alignment means for aligning the guide along a translational path and first and second rotational paths. This limitation is interpreted in accordance with 35 U.S.C. § 112, 6th paragraph. In this regard, the Examiner's attention is directed to the Federal Circuit decision in *In re Donaldson Co., Inc.*, 16 F.3d 1189 (Fed. Cir. 1994) *en banc*. The Federal Circuit held that § 112(6) applies not only in infringement determinations, but also in patentability determinations. It is well established that claims are to be given their broadest reasonable interpretation during prosecution. However, the Federal Circuit's decision set a limit on how broadly the United States Patent and Trademark Office can construe means plus function language under the rubric of reasonable interpretation. Specifically, the Federal Circuit held that the broadest reasonable interpretation that an Examiner may give means plus function language is that statutorally mandated in § 112(6). Therefore, one must construe means plus function language in a claim by looking to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalence thereof. Accordingly, the Examiner may not disregard the structure disclosed in Applicants' specification corresponding to the means plus function language when rendering a patentability determination. In the present case, this appears to be exactly what the Examiner has done.

As taught in the specification, the alignment means provides improvements in accurately aligning the cutting blade along a translational path and two rotational paths for resection of bone. (Specification p. 2). The alignment means is generally intended for any medical condition in which the use of computer-aided surgery may be appropriate, and where a reference to rigid anatomical structures, such as the femur or the tibia

can be identified. (*Id.* at 14). Specifically, the alignment guide 100 includes three assemblies to separately adjust the resection level along a translational path, and the varus-valgus and flexion-extension, which is coupled to the femoral and left-right tibial resection guides, along two rotational paths. (*Id.* at 8). With respect to the translational path, the resection level is adjusted by rotation of the threaded adjustment rod 168 by attaching a suitable implement to the engagement member 134 providing continuous variable adjustment. (*Id.* at 17).

> As the threaded rod 168 is rotated, the housing 114 of the adjustment assembly 102 is displaced in controlled increments away from the yoke 152 while being guided by the pair of spaced apart shafts 164. Due to the threaded engagement of the threaded rod 168 with the housing 114, the resection level of the resection cutting guide 104 can be controlled, as well as avoiding the need for a secondary locking or clamping assembly. (*Id.*)

As to the first rotational path, the use of the meshed gear-type arrangement in the varus-valgus adjustment assembly 108 allows for the precise controlled manipulation of the resection cutting guide 104 in controlled increments. (*Id.* at 16). "By selecting the design of the worm 132 and teeth 144 on the mounting bracket 136, precision control of aligning the resection guide for varus-valgus angle can be accomplished." (*Id.*) As to the second rotational path, the flexion-extension angle is adjusted using the flexion-extension adjustment assembly 112, which is coupled to the resection cutting guide 104. (*Id.*) Each rotation of sleeve 206, which is attached to the engagement member 134, will result in a predetermined linear advancement of the cross-member 214 in controlled increments. (*Id.* at 17). This advancement is

controlled by the pitch of the threads on the threaded rod 216 and the threads on the internally threaded sleeve 206. (*Id.*)

Pohl does not teach any corresponding or equivalent structure to perform these functions. For example, the Examiner contends that "The second assembly (14) allows for rotation about a first rotational path in controlled increments by turning the knob (32) in relation to the rod (14) and the device (10)." (Office Action p. 3-4). However, according to *Pohl*:

> As shown in FIGS. 2 and 3, the intramedullary rod 14 includes a rod portion 30 which is threaded at its distal end into a knurled knob 32. . . By inserting the rod 14 through the selected bore 60, the jig is positioned parallel to the rod 14. At this time, the knurled knob 32 can be threaded onto the rod end. (*Pohl* at col. 4 lns. 56-58, col. 6 lns. 54-57).

Thus, in the only two places where *Pohl* discusses knob 32, it is describes as merely an end cap fastened onto rod 14 after the device 10 has been assembled. Any rotation of the rod or knob would not result in rotation of the cutting plate or support plate. In fact, the rod 14 would not be rotatable at all as it is inserted through the intercondylar canal of the bone. (*Pohl* col. 6, lns. 45-48). Thus, unlike the present invention, wherein each assembly is adjusted in controlled increments by threaded member, *Pohl* does not teach an equivalent structure.

Like claim 1, claims 14 and 26 each recite alignment in controlled increments along a translational path, a first rotational path, and a second rotational path. As noted above, *Pohl* does not teach a device having controlled increment adjustment about a first rotational path because knob 32 is merely an end cap threaded onto rod 14, and not knob for controlled increment adjustment.

Claim 37 and claim 50 recite several elements which are not found in *Pohl*. For example, both claims recite a first assembly having an internally threaded sleeve rotationally coupled to an instrument guide. The rotation of the sleeve effects translation of the cross-member, thereby effecting manipulation of the instrument guide along a first rotational path. The Examiner seems to equate this with *Pohl*'s rod 14. (Office Action p. 3-4) According to the Examiner, rod 14 allows rotation about a first rotational path in controlled increments by turning knob 32 in relation to rod 14 and device 10. *Id.* As discussed above, *Pohl*'s knob 32 is merely an end cap to rod 14 and does not effect adjustment about a first rotational path. Moreover, in accordance with the Examiner's assertion, this assembly does not include a threaded sleeve rotationally coupled to an instrument guide. Even if the Examiner meant to include *Pohl*'s shaft 34, bolt 62 and guide bar 20 as part of the comparison of the first assembly of the present invention, *Pohl*'s shaft 34 is not rotationally coupled to an instrument guide and rotation of the shaft 34 does not effect translation of the guide bar/reference bar 20. Rather, the "reference bar may be slidably and pivotally positioned on the shaft 34. . . the reference bar may be pivoted about the shaft." (*Pohl* col. 5, lns. 51-56). Moreover, the bolt 62 is not used as a rotational coupler, but is "threaded into the lower end of the shaft 34 to retain the guide bar 20." (*Pohl* at col. 5, lns. 14-16).

Claims 37 and 50 of the present invention also recite that the second assembly includes a housing supporting a rotatable plate with a first portion having a first gear and the second portion coupled to the instrument guide and a rotatable second gear coupled to the first gear. The rotation of the second gear effects rotation of the plate, thereby effecting manipulation of the instrument guide along a second rotational path. The Examiner seems to equate this assembly with *Pohl*'s

fan-shaped portion 40, cutting plate 18, shaft 34, and boss 44, which, according to the Examiner, allows for controlled rotation about a second rotational axis in controlled increments affected by "gear/bolt" 86 and 88. (Office Action p. 4) However, *Pohl*'s device does not contain any gears. As defined in the specification, rotation of the second gear affects rotation of the plate. (Specification p. 4). In *Pohl*, where the Examiner has defined "screws" 86 and 88 as gears, the screws are used to "lock" the fan-shaped portion 40 into position once it has been adjusted. (*Pohl* col. 5, lns. 39-48). Thus, rotation of the screws, which are threaded into the locking holes to retain the position of the plate, do not effect rotation of the fan-shaped portion, as claimed in the present invention. *Id.* *Pohl* simply does not teach the same or equivalent elements as claimed in the present invention.

Claims 42 has been amended to include the limitations of claim 44 wherein each of the three assemblies is adjustable by rotation of a member. There is no member in *Pohl* for providing rotational adjustment of the jig. The only rotating members are the bolts 104 and 106, which affect translation of the cutting plate and support plate along rod 14.

As *Pohl* does not teach every element of the claims of the present invention, Applicants submit that it is not an anticipatory reference. Withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103(a)

The Examiner has also rejected claims 7-10, 19-22, 31-34 and 46-47 as obvious over *Pohl* in light of *Helland* (U.S. Patent No. 4,488,542). The Examiner contends that *Pohl* discloses each and every element of the present claims with the exception of a worm, which is taught by *Helland*. The Examiner believes that it would have been obvious to a person skilled in this art to combine the worm meshed with teeth as taught by

Helland, with the teachings of *Pohl* to create the present invention. (Office Action p. 6). Applicants respectfully disagree and traverse the rejection.

Helland is directed to a device for external correction and setting of bone parts at the site of a fracture. *Helland* uses worm wheel teeth and a worm attached to arc-shaped guides to affect rotation in two planes for adjustment of the device for setting bones. *Pohl* is directed to a device for resectioning a distal femoral surface to prepare that surface to accept a distal femoral prosthesis. *Pohl's* device incorporates a number of threaded screws, but no gears or worm devices for incremental adjustment. Moreover, *Pohl*'s device is used during a surgical procedure to cut the femoral surface, whereas *Helland*'s external device anchors bones in place over a period of time. Neither of these references teach, suggest, or even motivate one skilled in the art to combine a worm meshed with teeth as taught in Helland, with the device of *Pohl* to create a resectioning device as claimed in the present invention. See M.P.E.P. §706.02(j). The combination of the device of *Pohl* and worm of *Helland* can only be made through the use of hindsight reconstruction, which the Court of Appeals for the Federal Circuit has consistently stated is impermissible. *See In Re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991); *Interconnect Planning Corp. v. Feil*, 774, F.2d 1132, 1143 (Fed. Cir. 1985). Moreover, even if these references were combined, albeit improperly, the claimed invention would still not be produced because *Pohl* does not teach a device having controlled increment adjustment about a first rotational path, as claimed in the present invention. Thus, this combination of references is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: May 30, 2006

Respectfully submitted,

By _____
Stephen B. Goldman
Registration No.: 28,512
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicants

655782_1.DOC